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NOTICE OF ALLOWANCE AND FEE(S) DUE

24247

7500

02/28/2008

02/20/2000

TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110 EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT PAPER NUMBER

1795

DATE MAILED: 02/28/2008

	APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
Ī	10/764.270	01/23/2004	Ewa Maria Rogalska	2183-6294US	6555

TITLE OF INVENTION: METHOD OF BINDING A COMPOUND TO A SENSOR SURFACE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1440	\$300	\$0	\$1740	05/28/2008

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

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B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or <u>Fax</u> (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where

appropriate. All further indicated unless correcte maintenance fee notifica	ed below or directed oth	ng the Patent, advance on nerwise in Block 1, by (a	rders and notification of many specifying a new corresp	naintenance fees will be condence address; and	e mailed to the current or (b) indicating a sepa	correspondence address as rate "FEE ADDRESS" for
CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)			Fee(:	s) Transmittal. This ce	tificate cannot be used for	r domestic mailings of the or any other accompanying nt or formal drawing, must
24247 7590 02/28/2008 TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			I her State addr trans	eby certify that this Fe	ate of Mailing or Transi le(s) Transmittal is being sufficient postage for firs p ISSUE FEE address 571) 273-2885, on the da	mission deposited with the United t class mail in an envelope above, or being facsimile ate indicated below.
						(Depositor's name)
						(Signature)
						(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR	AT	TORNEY DOCKET NO.	CONFIRMATION NO.
10/764,270 TITLE OF INVENTION	01/23/2004 : METHOD OF BINDIN	NG A COMPOUND TO A	Ewa Maria Rogalska A SENSOR SURFACE		2183-6294US	6555
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nonprovisional	NO	\$1440	\$300	\$0	\$1740	05/28/2008
EXAM	INER	ART UNIT	CLASS-SUBCLASS			
NOGUEROLA, ALE	XANDER STEPHAN	1795	205-777500			
"Fee Address" ind PTO/SB/47; Rev 03-0 Number is required. 3. ASSIGNEE NAME A PLEASE NOTE: Unl	ondence address (or Cha 3/122) attached. ication (or "Fee Address)2 or more recent) attach ND RESIDENCE DATA less an assignee is ident h in 37 CFR 3.11. Com	nge of Correspondence "Indication form led. Use of a Customer A TO BE PRINTED ON This ified below, no assignee	2. For printing on the part (1) the names of up to or agents OR, alternative (2) the name of a single registered attorney or a 2 registered patent attorn listed, no name will be part (1) the PATENT (print or type data will appear on the part a substitute for filing and (B) RESIDENCE: (CITY)	3 registered patent attely, e firm (having as a mergent) and the names of neys or agents. If no norinted. e) tent. If an assignee is assignment.	mber a 2	ocument has been filed for
Please check the appropr	iate assignee category or	categories (will not be pr	rinted on the patent):	Individual 🖵 Corpor	ation or other private gro	oup entity Government
4a. The following fee(s) are submitted: ☐ Issue Fee ☐ Publication Fee (No small entity discount permitted) ☐ Advance Order - # of Copies			4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) ☐ A check is enclosed. ☐ Payment by credit card. Form PTO-2038 is attached. ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number (enclose an extra copy of this form).			
5. Change in Entity Star a. Applicant claim	tus (from status indicate s SMALL ENTITY statu	· · · · · · · · · · · · · · · · · · ·	☐ b. Applicant is no long	er claiming SMALL E	NTITY status. See 37 CF	FR 1.27(g)(2).
NOTE: The Issue Fee an interest as shown by the i	d Publication Fee (if req records of the United Sta	uired) will not be accepte tes Patent and Trademark	d from anyone other than the Office.	ne applicant; a registere	d attorney or agent; or th	e assignee or other party in
Authorized Signature				Date		
Typed or printed name				Registration No		
This collection of inform an application. Confident submitting the completed this form and/or suggesti Box 1450. Alexandria V	ation is required by 37 C tiality is governed by 35 d application form to the ions for reducing this bu	CFR 1.311. The informatic U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to the	on is required to obtain or re 1.14. This collection is esti depending upon the indivi e Chief Information Office: COMPLETED FORMS TO	etain a benefit by the primated to take 12 minu dual case. Any commer, U.S. Patent and Trace of THIS ADDRESS.	ublic which is to file (and tes to complete, includin ents on the amount of tin emark Office, U.S. Depar	by the USPTO to process) g gathering, preparing, and ne you require to complete urtment of Commerce, P.O. For Patents P.O. Box 1450.

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			ART UNIT	PAPER NUMBER	
SALT LAKE CITY	Y, UT 84110		1795		
			DATE MAILED: 02/28/200	8	

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 1072 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 1072 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)			
	10/764,270	ROGALSKA ET AL.			
Notice of Allowability	Examiner	Art Unit			
	ALEX NOGUEROLA	1795			
The MAILING DATE of this communication apperature All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in this ap or other appropriate communication IGHTS. This application is subject t	plication. If not included n will be mailed in due course. THIS			
1. 🔀 This communication is responsive to preliminary amendment	ent of 01/23/2004.				
2. The allowed claim(s) is/are <u>1-22</u> .					
 3. Acknowledgment is made of a claim for foreign priority upon a) All b) Some* c) None of the: 1. Certified copies of the priority documents have 2. Certified copies of the priority documents have 3. Copies of the certified copies of the priority documents have 	e been received. e been received in Application No				
International Bureau (PCT Rule 17.2(a)).					
* Certified copies not received:					
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.		complying with the requirements			
4. A SUBSTITUTE OATH OR DECLARATION must be subminFORMAL PATENT APPLICATION (PTO-152) which give					
5. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.					
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached					
1) 🔲 hereto or 2) 🔲 to Paper No./Mail Date					
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date					
Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in t					
6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.					
Attachment(s) 1. ☑ Notice of References Cited (PTO-892)	5. ☐ Notice of Informal F	Patent Application			
2. Notice of Draftperson's Patent Drawing Review (PTO-948)	6. ☐ Interview Summary				
3. ☑ Information Disclosure Statements (PTO/SB/08),	Paper No./Mail Da 7. ☐ Examiner's Amend	te .			
Paper No./Mail Date <u>4/14/2006</u> 4. ☐ Examiner's Comment Regarding Requirement for Deposit	<u></u>	ent of Reasons for Allowance			
of Biological Material	— 9.				

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DETAILED ACTION

Allowable Subject Matter

- 1. Claims 1-22 are allowed.
- 2. The following is an examiner's statement of reasons for allowance: each of the combinations of limitations in independent claims 1, 15, and 22 requires the compound to be non-covalently bound to the hydrophobin-like substance. Applicants have found that "[t]his mode of binding leaves the secondary and tertiary structure of such biological compounds virtually intact and, thus, allows improved biological recognition as compared to covalent binding methods which often alter such structural determinats." See the paragraph [0028] of the specification.

In the International Preliminary Examination Report for International application No. PCT/NL02/00411 claims 1-22 were recognized as being novel, but not inventive over references "D1-D6" as identified therein. The Examiner of the instant application disagrees with the European examiner's argument as to why the claimed invention is not inventive. The European examiner states that it was well known to coat a sensor surface with bilayer lipid membranes, as shown by references D1 and D2, for example. Next the European examiner states that reference D6 shows that it was known to use

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self-assembled monolayers of proteins to immobilize biologically functional macromolecules on biosensors either covalently or non-covalently. The European examiner then states it was known that hydrophobins form self-assembling, amphipatic films which are suitable for attaching molecules thereby to the surfaces as shown by references D3, D4, and D5. From these statements the European examiner concludes that the substitution of hydrophobins for a lipid bilayer in a sensor is not inventive.

Reference D6, however, makes not mention sensors. The disclosed uses of the self-assembled monolayers of proteins are for nanoelectronics or nonlinear optics, such as transistors or quantum-dot lasers. See the abstract and "Conclusion and perspectives" on page 11. Moreover, reference D6 does not mention hydrobins, but discusses bacterial S-layer proteins, which are "... composed of a single protein or glycoprotein species, with molecular weights from 40 to 200kDa. The crystalline arrays exhibit either oblique, square or hexagonal lattice symmetry ... " See the first paragraph of "Characteristics of S-layers". In contrast, "[h]ydrophobins are small proteins (100±25 amino acids) that are moderately hydrophobic ...have a conserved spacing of eight cysteine residues: X₂₋₃₈-C-X₅₋₉-C-C-X₁₁₋₃₉-C-X₈₋₂₃-C-X₅₋₉-C-C-X₆₋₁₈-C-X₂₋₁₃ in which X signifies any other amino acid ... " See in reference D3 item 1 on page 6 and item 3 on page 8. Thus, S-layer proteins are defined differently than hydrophins and do not suggest hydrophobins or properties that hydrophobins may have.

Reference D3 does actually disclose coating at least a part of a surface of a sensor with a hydrophobin-like substance and contacting the hydrophobin-like substance with a compound to form a bond between the hydrophobin-like substance

and the compound. However, the bond formed between the compound and the hydrophobin-like substance is a covalent bond resulting from oxidizing mannose residues with periodic acid and coupling the generated aldehyde groups to amino acid groups of a protein by a Schiff-base reaction. See item 2 on page 35 of reference D3.

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As for references D4 and D5, reference D4 does not mention sensors and so does not mention coating a sensor surface with hydrophobin and also does not mention bonding a compound to a hydrophobin coating. Reference D5 only mentions that hydrophobins could be used as a coating in medical devices, such as catheters, and that "[a]ttachment [of molecules] could be achieved by chemical cross-linking after the hydrophobin has been assembled on the surface [of the medical device]." See the second column on page 3.

Thus, the examiner of the instant application does not agree with the European examiner that hydrophobin is an obvious alternative to lipid bilayers as a sensor surface coating

De Vocht et al. US 2003/0134042 A1 was not cited by the European examiner. It is relevant because it discloses coating a biosensor with hydrophobin. However, the disclosure is very broad in that "biosensor" is only in a list of objects that may be coated including other objects such as a window, a contact lens, a medical device, a container for performing an assay or storage, the hull of a vessel or a frame or bodywork of a car, and a solid particle. See paragraphs [0002] and [0005]. Also, de Vocht does not mention non-covalently attaching a compound to a hydrophobin.

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Any comments considered necessary by applicant must be submitted no later

than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on

Statement of Reasons for Allowance."

3. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-

1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Alex Noguerola/

Primary Examiner, Art Unit 1795

February 19, 2008